SUBCOMMITTEE: SUBCOMMITTEE #1

HOUSE BILL NO. 532

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on/for _____

on _____)

(Patron Prior to Substitute--Delegate Freitas)

A BILL to amend and reenact §§ 3.2-4112 through 3.2-4119 and 54.1-3401, as it is currently effective and as it shall become effective, of the Code of Virginia; to amend the Code of Virginia by adding sections numbered 3.2-4114.1 and 3.2-4114.2; and to repeal § 3.2-4120 of the Code of Virginia, relating to industrial hemp; research.

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4112 through 3.2-4119 and 54.1-3401, as it is currently effective and as it shall become effective, of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 3.2-4114.1 and 3.2-4114.2 as follows:

§ 3.2-4112. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Grow" means to plant, cultivate, or harvest a plant or crop.

"Grower" means any person ~~licensed~~ registered pursuant to subsection A of § 3.2-4115 to grow industrial hemp ~~as part of the industrial hemp research program~~.

"Hemp ~~products~~ product" means ~~all products~~ a product made from industrial hemp~~, including cloth, cordage, fiber, food, fuel, paint, paper, particleboard, plastics, seed, seed meal and seed oil for consumption, and seed for cultivation~~.

"Higher education industrial hemp research program" means a research program established pursuant to subsection A of § 3.2-4114.1.

"Industrial hemp" means all parts and varieties of the plant Cannabis sativa, ~~cultivated or possessed by a licensed grower,~~ whether growing or not, that contain a concentration of ~~THC~~ tetrahydrocannabinol

that is no greater than that allowed by federal law. ~~Industrial hemp as defined and applied in this chapter is excluded from the definition of marijuana as found in § 54.1-3401.~~

~~"Industrial hemp research program" means the research program established pursuant to § 3.2-4120.~~

~~"Seed research" means research conducted to develop or re-create better varieties of industrial hemp, particularly for the purposes of seed production.~~

~~"Tetrahydrocannabinol" or "THC" means the natural or synthetic equivalents of the substances contained in the plant, or in the resinous extractives, of the genus Cannabis, or any synthetic substances, compounds, salts, or derivatives of the plant or chemicals and their isomers with similar chemical structure and pharmacological activity.~~

"Process" means to convert industrial hemp into a marketable form.

"Processor" means a person registered pursuant to subsection A of § 3.2-4115 to process industrial hemp.

"Process site" means the location at which a processor processes or intends to process industrial hemp.

"Production field" means the land or area on which a grower is growing or intends to grow industrial hemp.

"Virginia industrial hemp research program" means the research program established pursuant to subsection B of § 3.2-4114.1.

§ 3.2-4113. Production of industrial hemp lawful.

A. It is lawful for a ~~person licensed pursuant to § 3.2-4115 or 3.2-4117 to cultivate, produce, or otherwise grow~~ grower or his agent to grow or a processor or his agent to process industrial hemp in the Commonwealth for any lawful purpose, including the manufacture of ~~industrial~~ a hemp ~~products~~ product or scientific, agricultural, or other research related to other lawful applications for industrial hemp. No ~~person licensed pursuant to § 3.2-4115 or 3.2-4117~~ grower or his agent or processor or his agent shall be prosecuted under § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, 18.2-250, or 18.2-250.1 for the possession, ~~cultivation, or manufacture~~ growing, or processing of industrial hemp ~~plant material and seeds~~

~~or industrial hemp products~~. In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2 or the Drug Control Act (§ 54.1-3400 et seq.), it shall not be necessary to negate any exception, excuse, proviso, or exemption contained in this chapter or the Drug Control Act, and the burden of proof of any such exception, excuse, proviso, or exemption shall be on the defendant.

B. Nothing in this chapter shall be construed to authorize any person to violate any federal law or regulation. If any part of this chapter conflicts with a provision of federal law relating to industrial hemp ~~that has been adopted in Virginia under this chapter~~, the federal provision shall control to the extent of the conflict.

C. No person shall be prosecuted under § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, 18.2-250, or 18.2-250.1 for the involuntary growth of industrial hemp through the inadvertent natural spread of seeds or pollen as a result of proximity to a ~~licensed grower or a grower licensed pursuant to § 3.2-4117~~ production field or process site.

§ 3.2-4114. Regulations.

The Board may adopt regulations pursuant to this chapter as necessary to ~~(i) license~~ register persons to grow or process industrial hemp or ~~(ii) administer the industrial hemp research program~~ implement the provisions of this chapter.

§ 3.2-4114.1. Higher education industrial hemp research programs; Virginia industrial hemp research program.

A. To the extent that adequate funds are available, the Commissioner may undertake research of industrial hemp growth, processing, or marketing through the establishment and oversight of higher education industrial hemp research programs, which shall be directly managed by institutions of higher education in the Commonwealth. Any institution of higher education directly managing a higher education industrial hemp research program shall, by October 1 of each year, submit a report to the Commissioner regarding the institution's growing or processing activities for the previous year.

B. To the extent that adequate funds are available, the Commissioner may undertake research of industrial hemp growth, processing, or marketing through the establishment and management of the Virginia industrial hemp research program.

C. Each participant in a research program established pursuant to this section shall be registered pursuant to subsection A of § 3.2-4115 prior to growing or processing any industrial hemp.

D. The research activities undertaken pursuant to this section shall not:

1. Subject any industrial hemp research program established pursuant to this section to any criminal liability under the controlled substances laws of the Commonwealth. This exemption from criminal liability is a limited exemption that shall be strictly construed and that shall not apply to any activities of such an industrial hemp research program that are not authorized; or

2. Alter, amend, or repeal by implication any provision of this Code relating to controlled substances.

§ 3.2-4114.2. Authority of Commissioner; notice to law enforcement; report.

A. The Commissioner may charge a nonrefundable fee not to exceed $50 for (i) any application for registration or renewal of registration allowed under this chapter and (ii) tetrahydrocannabinol testing allowed under this chapter. All fees collected by the Commissioner shall be deposited in the state treasury.

B. The Commissioner may establish a minimum size for a production field that shall qualify a person for a Virginia industrial hemp research program grower registration.

C. The Commissioner shall notify the Superintendent of State Police of the locations of all industrial hemp production fields and process sites.

D. The Commissioner shall forward a copy or appropriate electronic record of each registration issued by the Commissioner under this chapter to the chief law-enforcement officer of the county or city where industrial hemp will be grown or processed.

E. The Commissioner shall be responsible for monitoring the industrial hemp grown or processed by a person registered pursuant to subsection A of § 3.2-4115 and shall provide for random testing of the industrial hemp, at the cost of the grower or processor, for compliance with tetrahydrocannabinol limits and for other appropriate purposes established pursuant to § 3.2-4114. In addition to any routine inspection

and sampling, the Commissioner may inspect and sample the industrial hemp at any production field or process site during normal business hours without advance notice if he has reason to believe a violation of this chapter is occurring or has occurred.

F. The Commissioner may require a grower or processor to destroy, at the cost of the grower or processor and in a manner approved of and verified by the Commissioner, any Cannabis sativa that the grower grows or the processor processes that has been tested and is found to have a concentration of tetrahydrocannabinol that is greater than that allowed by federal law.

G. The Commissioner may advise the Superintendent of State Police or the chief law-enforcement officer of the appropriate county or city when a grower grows or a processor processes any Cannabis sativa with a concentration of tetrahydrocannabinol that is greater than that allowed by federal law.

H. The Commissioner may pursue any permits or waivers from the U.S. Drug Enforcement Administration or appropriate federal agency that he determines to be necessary for the advancement of a higher education industrial hemp research program or the Virginia industrial hemp research program.

I. The Commissioner may cooperatively seek funds from public and private sources to implement a higher education industrial hemp research program or the Virginia industrial hemp research program.

J. By December 1 of each year, the Commissioner shall report on the status and progress of any higher education industrial hemp research program and the Virginia industrial hemp research program to the Governor and to the General Assembly and shall submit such report for publication as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports.

§ 3.2-4115. Issuance of registrations.

A. The Commissioner shall establish a registration program ~~of licensure~~ to allow a person to grow or process industrial hemp in the Commonwealth in a controlled fashion solely and exclusively as part of ~~the~~ a higher education industrial hemp research program or the Virginia industrial hemp research program. ~~This form of licensure shall only be allowed subject to a grant of necessary permissions, waivers, or other form of valid legal status by the U.S. Drug Enforcement Administration or other appropriate federal agency pursuant to applicable federal laws relating to industrial hemp.~~

B. Any person seeking to grow or process industrial hemp as part of ~~the~~ a higher education industrial hemp research program or the Virginia industrial hemp research program shall apply to the Commissioner for a ~~license~~ registration on a form provided by the Commissioner. At a minimum, the application shall include:

1. The name and mailing address of the applicant;

2. The legal description and geographic data sufficient for locating ~~the production fields to be used~~ (i) the land on which the applicant intends to grow industrial hemp~~. A license~~ or (ii) the site at which the applicant intends to process industrial hemp. A registration shall authorize industrial hemp ~~propagation~~ growth or processing only ~~on the land areas~~ at the location specified in the ~~license~~ registration;

3. A signed statement indicating whether the applicant has ever been convicted of a felony. A person with a prior felony drug conviction within 10 years of applying for a ~~license~~ registration under this section shall not be eligible ~~for the license~~ to be registered;

4. Written consent allowing the sheriff's office, police department, or Department of State Police, if a ~~license~~ registration is ultimately issued to the applicant, to enter the premises on which the industrial hemp is grown or processed to conduct physical inspections of the industrial hemp ~~planted and grown by the applicant~~ and to ensure compliance with the requirements of this chapter. No more than two physical inspections shall be conducted under this subdivision per year, unless a valid search warrant for an inspection has been issued by a court of competent jurisdiction~~. All testing for THC levels shall be performed as provided in subsection K~~;

5. ~~Documentation~~ If the applicant intends to participate in a higher education industrial hemp research program, documentation of an agreement between ~~a public~~ an institution of higher education and the applicant that states that the applicant, if ~~licensed~~ registered pursuant to ~~this section~~ subsection A, will be a participant in the higher education industrial hemp research program managed by that ~~public~~ institution of higher education;

6. Written consent allowing the Commissioner or his designee to enter the premises on which the industrial hemp is grown or processed to conduct inspections and sampling of the industrial hemp to ensure compliance with the requirements of this chapter;

7. If the applicant intends to participate in the Virginia industrial hemp research program, a statement of the approximate square footage or acreage of the location he intends to use as a production field or process site and a description of the research he plans to conduct to advance the industrial hemp industry;

8. Any other information required by the Commissioner; and

~~7.~~ 9. The payment of a nonrefundable application fee, in an amount set by the Commissioner not to exceed $50.

C. ~~The Commissioner shall require a state and national fingerprint-based criminal history background check by the Department of State Police on any person applying for licensure. The Department of State Police may charge a fee, as established by the Department of State Police, to be paid by the applicant for the actual cost of processing the background check. A copy of the results of the background check shall be sent to the Commissioner.~~

~~D. All license applications shall be processed as follows:~~

~~1. Upon receipt of a license application, the Commissioner shall forward a copy of the application to the Department of State Police, which shall initiate its review thereof;~~

~~2. The Department of State Police shall, within 60 days, perform the required state and national criminal history background check of the applicant; approve the application, if it is determined that the requirements relating to prior criminal convictions have been met; and return all applications to the Commissioner together with its findings and a copy of the state and national criminal history background check; and~~

~~3. The Commissioner shall review all license applications returned from the Department of State Police. If the Commissioner determines that all requirements have been met and that a license should be granted to the applicant, taking into consideration any prior convictions of the applicant, the Commissioner shall approve the application for issuance of a license.~~

~~E. The Commissioner may approve licenses for only those selected growers whose demonstration plots will, in the discretion of the Commissioner, advance the goals of the industrial hemp research program to the furthest extent possible based on location, soil type, growing conditions, varieties of~~

~~industrial hemp and their suitability for particular hemp products, and other relevant factors. The location and acreage of each demonstration plot to be grown by a license holder, as well as the total number of plots to be grown by a license holder, shall be determined at the discretion of the Commissioner.~~

~~F. An industrial hemp research program grower license shall not be subject to a minimum acreage.~~

~~G.~~ Each ~~license~~ registration issued pursuant to this section shall be valid for a period of one year from the date of issuance and may be renewed in successive years. Each annual renewal shall require the payment of a ~~license~~ registration renewal fee, in an amount set by the Commissioner not to exceed $50.

~~H. The Commissioner shall establish the fee amounts required for license applications and license renewals allowed under this section. All application and license renewal fees collected by the Commissioner shall be deposited in the State Treasury.~~

~~I. A copy or appropriate electronic record of each license issued by the Commissioner under this section shall be forwarded immediately to the chief law enforcement officer of each county or city where the industrial hemp is licensed to be planted, grown, and harvested.~~

~~J.~~ D. All records, data, and information filed in support of a ~~license~~ registration application submitted pursuant to this section shall be considered proprietary and excluded from the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.).

~~K. The Commissioner shall be responsible for monitoring the industrial hemp grown by any license holder and shall provide for random testing of the industrial hemp for compliance with THC levels and for other appropriate purposes established pursuant to § 3.2-4114 at the cost of the license holder.~~

§ 3.2-4116. Registration conditions.

A. A person shall obtain ~~an industrial hemp grower license~~ a registration pursuant to subsection A of § 3.2-4115 prior to ~~planting or~~ growing or processing any industrial hemp in the Commonwealth.

B. A person ~~granted an industrial hemp grower license~~ issued a registration pursuant to subsection A of § 3.2-4115 shall:

1. Maintain records that reflect compliance with this chapter and with all other state laws regulating the ~~planting and cultivation~~ growing or processing of industrial hemp;

2. Retain all industrial hemp ~~production~~ growing or processing records for at least three years;

3. Allow ~~industrial hemp crops, throughout sowing, growing, and harvesting,~~ his production field or process site to be inspected by and at the discretion of the Commissioner or his designee, the Department of State Police, or the chief law-enforcement officer of the locality in which the production field or process site exists; ~~and~~

4. Allow the Commissioner or his designee to monitor and test the grower's or processor's industrial hemp for compliance with tetrahydrocannabinol levels and for other appropriate purposes established pursuant to § 3.2-4114, at the cost of the grower or processor;

5. If the person is a participant in a higher education industrial hemp research program, maintain ~~Maintain~~ a current written agreement with ~~a public~~ an institution of higher education that states that the grower or processor is a participant in the higher education industrial hemp research program managed by that ~~public~~ institution of higher education;

6. If required by the Commissioner, destroy, at the cost of the grower or processor and in a manner approved of and verified by the Commissioner, any Cannabis sativa that the grower grows or the processor processes that has been tested and is found to have a concentration of tetrahydrocannabinol that is greater than that allowed by federal law; and

7. If the person is a participant in the Virginia industrial hemp research program, by October 1 of each year, submit a report to the Commissioner regarding his growing or processing activities for the previous year.

§ 3.2-4117. Additional industrial hemp registration.

~~A. The~~ If applicable federal laws allow the growth or processing of industrial hemp for commercial purposes in the United States, the Board may adopt regulations as necessary to ~~license~~ register persons to grow or process industrial hemp in the Commonwealth for any ~~lawful~~ purpose~~.~~

~~B. Notwithstanding the provisions of §§ 3.2-4115 and 3.2-4116~~, and the Commissioner ~~shall~~ may establish a registration program ~~of licensure and renewal~~, including the establishment of any fees not to exceed ~~$250~~ $50, to allow a person to grow or process industrial hemp in the Commonwealth for any ~~lawful~~ purpose. ~~Valid applications shall be granted licensure within 90 days of receipt of the application.~~

~~The Commissioner shall accept license applications throughout the year. Licenses shall be valid for four years from the date of the issuance of the license.~~

§ 3.2-4118. Forfeiture of industrial hemp grower or processor registration.

A. The Commissioner shall deny the application, or suspend or revoke the ~~license~~ registration, of any ~~industrial hemp grower if the grower~~ person who violates any provision of this chapter. The Commissioner shall provide reasonable notice of an informal fact-finding conference pursuant to § 2.2-4019 to any ~~industrial hemp grower~~ person in connection with the denial, suspension, or revocation of ~~the grower's license~~ a registration.

B. If a ~~license~~ registration is revoked as the result of an informal hearing, the decision may be appealed, and upon appeal an administrative hearing shall be conducted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). The grower or processor may appeal a final order to the circuit court in accordance with the Administrative Process Act.

C. The Commissioner may revoke any ~~license~~ registration of any ~~person~~ grower or processor who has pled guilty to, or been convicted of, a felony.

§ 3.2-4119. Eligibility to receive tobacco settlement funds.

Industrial hemp growers ~~licensed~~ or processors registered under this chapter may be eligible to receive funds from the Tobacco Indemnification and Community Revitalization Fund established pursuant to § 3.2-3106.

§ 54.1-3401. (Effective until July 1, 2020) Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns

or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled

substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1

et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical

synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed~~, cultivated, or manufactured~~ by a ~~grower licensed~~ person registered pursuant to subsection A of § 3.2-4115 or his agent.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning -- may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3401. (Effective July 1, 2020) Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine

or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to

any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 C.F.R. Part 1300.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed~~, cultivated, or manufactured~~ by a ~~grower licensed~~ person registered pursuant to subsection A of § 3.2-4115 or his agent.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not

including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article

4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning -- may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and

Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

2. That § 3.2-4120 of the Code of Virginia is repealed.

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